



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0383]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Radioactive Drug Research Committees--(OMB Control Number 0910-0053)--Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees (RDRC) and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the RDRC, using Form FDA 2914, and a summary of each study conducted during the preceding year, using Form FDA 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the RDRC all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910-0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual RDRC, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

In the Federal Register of January 27, 2014 (79 FR 4348), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Sections/Forms	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
361.1(c)(3) & (4); Form FDA 2914	69	1	69	1	69
361.1(c)(3); Form FDA 2915	48	10	480	3.5	1,680
361.1(d)(8)	10	5	50	0.5 (30 minutes)	25
Total					1,774

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	18	630	0.75 (45 minutes)	472.5
Total					3,232.5

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.